Reply to Office Action of: March 29, 2006

CLAIMS

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. [[deletion]]) and new text is identified in bold with underlining (e.g. new language).

- 1. (Currently Amended) A medical lead for electrical stimulation or sensing, the medical lead comprising:
 - a generally round or tubular lead body having proximal and distal ends, and at least one electrical conductor extending between the proximal and distal ends;
 - a connector on the proximal end of the lead body in electrical communication with the electrical conductor; and
 - a generally flat paddle on the distal end of the lead body having an electrode array comprising at least one electrode in electrical communication with the electrical conductor, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being [[displaced]] offset along the length of the paddle toward the distal end such that the portion of the flat paddle proximal of the electrode array has a length of at least 1-1/2 inches (40mm), whereby the electrode array may be advanced into position for electrical stimulation or sensing with the portion of the flat paddle proximal of the electrode array extending through connective tissue, such as the ligamentum flavum.
- 2. (Currently Amended) The medical lead of claim 1 in which the flat paddle has opposite major surfaces and electrode apertures in one of the major surfaces, and the electrode array comprises a plurality of electrodes [[(e.g., 4 or 8 electrodes)]] exposed through electrode apertures.
- 3. (Original) The medical lead of claim 2 in which the electrode array comprises at least four electrodes.

Reply to Office Action of: March 29, 2006

4. (Original) The medical lead of claim 3 in which the electrode array comprises at least eight electrodes.

- 5. (Original) The medical lead of claim 2 in which the electrode array comprises four through eight electrodes.
- 6. (Original) The medical lead of claim 2 in which the electrodes are recessed relative to the major surface.
- 7. (Original) The medical lead of claim 1 further comprising a butt joint connecting the generally flat paddle with the generally round or tubular lead body.
- 8. (Original) The medical lead of claim 1 in which the connector comprises at least one ring contact in electrical communication with the electrical conductor.
- 9. (Original) The medical lead of claim 8 in which the connector comprises a plurality of ring contacts in electrical communication with the electrical conductor.
- 10. (Original) The medical lead of claim 8 in which the plurality of ring contacts are separated by electrically insulting ring spacers.
- 11. (Original) The medical lead of claim 8 in which the ring contact is attached to the conductor by a laser weld.
- 12. (Original) The medical lead of claim 1 in which the paddle has a lateral direction perpendicular to its length, the electrode having a lateral edge attached to the electrical conductor to provide an off-center connection tending to cause the electrode to spin in response to a tensile load provided by the electrical conductor rather than apply a direct tensile load tending to displace the electrode.

Reply to Office Action of: March 29, 2006

- 13. (Original) The medical lead of claim 12 in which the flat paddle is formed by two flat portions, at least one of the flat portions having internal surface features adapted to position the electrode and conductor, the flat portions being assembled together with the electrode and conductor and bonded together.
- 14. (Original) The medical lead of claim 13 in which the flat portions include at least one groove forming a passageway for a stylet after assembly and bonding of the paddle.
- 15. (Original) The medical lead of claim 13 in which each flat portion comprises at least two sections butt bonded together to form the flat portion.
- 16. (Original) The medical lead of claim 15 in which the butt bonds of the flat portions are offset from one another.
- 17. (Original) The medical lead of claim 16 in which the butt bonds extend generally across the width of the paddle, and the butt bonds are offset from one another along the length of the paddle.
- 18. (Original) The medical lead of claim 1 in which the portion of the flat paddle proximal of the electrode array has a length of at least 4 inches (100mm).
- 19. (Original) The medical lead of claim 1 in which the portion of the flat paddle proximal of the electrode array has a length of at least 3 inches (75mm).
- 20. (Original) The medical lead of claim 1 in which the portion of the flat paddle proximal of the electrode array has a length of at least 2 inches (50mm).
- 21. (Canceled)

Reply to Office Action of: March 29, 2006

22. (Original) A medical lead system comprising the medical lead of claim 2 and an anchor adapted for clamping the flat paddle and anchoring it to connective tissue, such as the ligamentum flavum.

- 23. (Original) The medical lead system of claim 22 in which the anchor comprising two clamping jaws adapted to clamp the major surfaces of the flat paddle therebetween.
- 24. (Currently Amended) [[The]] A medical lead system [[of claim 23 in which]] comprising a medical lead for electrical stimulation or sensing, the medical lead comprising:
 - a generally round or tubular lead body having proximal and distal ends, and
 at least one electrical conductor extending between the proximal and
 distal ends;
 - <u>a connector on the proximal end of the lead body in electrical communication</u> with the electrical conductor; and
 - a generally flat paddle on the distal end of the lead body having an electrode array comprising at least one electrode in electrical communication with the electrical conductor, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being displaced along the length of the paddle toward the distal end, whereby the electrode array may be advanced into position for electrical stimulation or sensing with the flat paddle extending through connective tissue, such as the ligamentum flavum, the flat paddle having opposite major surfaces and electrode apertures in one of the major surfaces, and the electrode array comprises a plurality of electrodes exposed through electrode apertures; and

an anchor adapted for clamping the flat paddle and anchoring it to connective tissue, such as the ligamentum flavum, the anchor comprising two clamping jaws adapted to clamp the major surfaces of the flat paddle therebetween, at least one of the clamping [[arms]] jaws is provided with at least one rib adapted to engage the flat paddle and retain it in position.

Reply to Office Action of: March 29, 2006

25. (Currently Amended) The medical lead system of claim 24 in which a plurality of ribs are provided on at least one clamping [[arm]] jaw to engage the flat paddle and retain it in position.

- 26. (Currently Amended) The medical lead system of claim 25 in which the clamping [[arms]] <u>jaws</u> are separable, the clamping [[arms]] <u>jaws</u> being provided with mating knobs and cavities for attaching the clamping [[arms]] <u>jaws</u> together.
- 27. (Original) The medical lead system of claim 23 in which the clamping jaws are pivotably connected to one another for movement between:
 - a closed position for clamping the major surfaces of the paddle therebetween; and an open position in which the anchor may be moved relative to the paddle.
- 28. (Original) A medical lead of claim 1 in which the lead body includes a strut having a stylet lumen and a plurality of channels for receiving the conductors, the strut being butt bonded to the paddle.
- 29. (Original) A medical lead of claim 1 in which the paddle is formed of polyurethane.
- 30. (Currently Amended) A medical lead for electrical stimulation or sensing, the medical lead comprising:
 - a generally round or tubular lead body having proximal and distal ends, and at least one electrical conductor extending between the proximal and distal ends;
 - a connector on the proximal end of the lead body in electrical communication with the electrical conductor; and
 - a generally flat paddle on the distal end of the lead body having an electrode array comprising at least one electrode in electrical communication with the electrical conductor, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being [[displaced]] offset along the length of the paddle toward the distal end such

Reply to Office Action of: March 29, 2006

that the portion of the flat paddle proximal of the electrode array has a length of at least 1-1/2 inches (40mm).

- 31. (Original) The medical lead of claim 30 in which the portion of the flat paddle proximal of the electrode array has a length of at least 2 inches (50mm).
- 32. (Original) The medical lead of claim 30 in which the portion of the flat paddle proximal of the electrode array has a length of at least 3 inches (75mm).
- 33. (Original) The medical lead of claim 30 in which the portion of the flat paddle proximal of the electrode array has a length of at least 4 inches (100mm).
- 34. (Original) A medical lead system for electrical stimulation or sensing, the medical lead system comprising:
 - a medical lead comprising:
 - a generally round or tubular lead body having proximal and distal ends, and at least one electrical conductor extending between the proximal and distal ends;
 - a connector on the proximal end of the lead body in electrical communication with the electrical conductor; and
 - a generally flat paddle on the distal end of the lead body having an electrode array comprising at least one electrode in electrical communication with the electrical conductor, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being displaced along the length of the paddle toward the distal end; and
 - an anchor configured for attachment to the paddle to anchor the paddle relative to biological tissue.
- 35. (Original) The medical lead system of claim 34 in which the flat paddle has opposite major surfaces, and the anchor comprises two clamping jaws adapted to clamp the major surfaces of the flat paddle therebetween.

Reply to Office Action of: March 29, 2006

36. (Original) The medical lead system of claim 35 in which at least one of the clamping arms is provided with at least one rib adapted to engage the flat paddle and retain it in position.

- 37. (Original) The medical lead system of claim 36 in which a plurality of ribs are provided on at least one clamping arm to engage the flat paddle and retain it in position.
- 38. (Original) The medical lead system of claim 37 in which the clamping arms are separable, the clamping arms being provided with mating knobs and cavities for attaching the clamping arms together.
- 39. (Original) The medical lead system of claim 35 in which the clamping jaws are pivotably connected to one another for movement between:
 - a closed position for clamping the major surfaces of the paddle therebetween; and an open position in which the anchor may be moved relative to the paddle.
- 40. (Original) A method of use of a medical lead having a generally flat paddle with an electrode array comprising at least one electrode, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being displaced along the length of the paddle toward the distal end, the method comprising:

percutaneously introducing distal end of the paddle generally anteriorly through the ligamentum flavum into an epidural space of a patient through a needle with the proximal end of the paddle remaining on the posterior side of the ligamentum flavum; and

anchoring the paddle to the posterior side of the ligamentum flavum.

41. (Original) The method of claim 40 wherein the step of anchoring the paddle to the posterior side of the ligamentum flavum comprises attaching an anchor to the paddle of the medical lead.

Reply to Office Action of: March 29, 2006

42. (Original) The method of claim 40 in which the paddle has opposite major surfaces, and the anchor comprises two clamping jaws, the step of attaching an anchor to the paddle of the medical lead comprising clamping the major surfaces of the paddle between the clamping jaws.

- 43. (Currently Amended) The method of claim 42 in which at least one of the clamping [[arms]] jaws is provided with at least one rib, the step of clamping the major surfaces of the flat paddle between the clamping jaws including engaging at least one of the major surfaces of the paddle with the rib to retain the paddle in position relative to the anchor.
- 44. (Currently Amended) The method of claim 43 in which a plurality of ribs are provided on at least one clamping [[arm]] <u>iaw</u>, the step of engaging at least one of the major surfaces of the paddle with the rib to retain the paddle in position relative to the anchor including engaging at least one of the major surfaces of the paddle with the plurality of ribs.
- 45. (Currently Amended) The method of claim 41 in which the clamping arms are separable, the clamping [[arms]] jaws being provided with mating knobs and cavities for attaching the clamping arms together, the step of attaching an anchor to the paddle of the medical lead including mating the mating knobs and cavities of the clamping [[arms]] jaws together to attach the clamping [[arms]] jaws together.
- 46. (Currently Amended) The method of claim 41 in which the clamping jaws are pivotably connected to one another, the step of attaching the anchor to the paddle including pivoting the clamping jaws from an [[n]] open position in which the anchor may be moved relative to the paddle to a closed position for clamping the major surfaces of the paddle therebetween.
- 47. (Original) The method of claim 40 further comprising removing the needle while leaving the lead in position.
- 48. (Original) The method of claim 47 wherein the needle has a lumen having a continuous oblong cross section adapted to receive the paddle of the medical lead.

Reply to Office Action of: March 29, 2006

- 49. (Original) The method of claim 40 further comprising repositioning the paddle.
- 50. (Original) The method of claim 40 further comprising explanting the medical lead without cutting through or dissecting the ligamentum flavum.
- A method of use of a medical lead having a generally flat paddle with an electrode array comprising at least one electrode, the paddle having proximal and distal ends and a length extending between the proximal and distal ends, the electrode array being displaced along the length of the paddle toward the distal end, the method comprising:

percutaneously introducing distal end of the paddle with an introducer needle generally through connective tissue into a desired stimulation or sensing site in a patient with the proximal end of the paddle left extending out from the connective tissue; and anchoring the paddle to the connective tissue.

- 52. (Original) The method of claim 51 further comprising removing the needle while leaving the lead in position.
- 53. (Original) The method of claim 52 wherein the needle has a lumen having a continuous oblong cross section adapted to receive the paddle of the medical lead.
- 54. (Original) The method of claim 53 further comprising repositioning the paddle.
- 55. (Original) The method of claim 51 further comprising explanting the medical lead without cutting through or dissecting the connective tissue.